

HEALTH ADVOCACY BULLETIN

The Journal of the Health Advocacy Program at Sarah Lawrence College

VOLUME 11, NUMBER 2

FALL 2003

Beyond the Bull's-Eye: Advocates Take Aim at Lyme Disease

By Yvonne Bokhour

How much do you know about Lyme disease? Are you aware of its symptoms? Do you believe blood tests are reliable? How quickly do you think Lyme can be cured? Many of my neighbors have discovered the answers to these questions the hard way. They are ill, or their children are ill, or both. As they try to cope, they find themselves immersed in two battles: the fight to be well and the fight to be heard.

Lyme disease is an illness shrouded by uncertainty and controversy. Disagreements abound within the medical community, leaving patients caught in the middle. Their anguish, especially as Lyme proliferates nationwide, points to the urgent need for research.

In 1997, a tiny group of neighbors met in Wilton, Connecticut. We were all victims of the illness, and we were all worried by its spread. We were especially troubled by the threat Lyme posed to our children, who were exposed to ticks every day. To prevent more cases and help

those afflicted, we arranged a seminar. Although we knew Lyme was prevalent, we were astonished by the turnout: 650 people filled Middlebrook auditorium. Volunteers soon found themselves fielding desperate calls from patients throughout Wilton, the tri-state area and indeed the nation. The Wilton Lyme Disease Support Group was then established to comfort those in need. Three years later, we launched a group for young people. Today, both are committed to providing emotional support to adults and teenagers in Fairfield County and beyond. Five hundred victims have now passed through our doors.

Lyme patients have an illness that is not only mysterious but also the focus of heated debate. As we contend with a wide array of frightening symptoms, we are trying to prove our illness is real.

The Controversy

At issue: whether Lyme is easy to spot and easy to cure. Many doctors believe it is. A fair number of patients see a bull's-eye rash, the best diagnostic

marker available. It seems most diagnosed at this point do quite well.

But how often does the rash occur, and how often is it missed? How reliable are testing methods? Are standard antibiotic doses sufficient? What should be done when symptoms persist after treatment? All of these questions and more are in dispute. The implications—medical, financial and emotional—are enormous. Surveys in some communities show as many as 54% of households affected. The Centers for Disease Control and Prevention (CDC) states that national incidence rates nearly doubled from 1991 to 2000. In fact, an analysis of recent CDC data reveals rates climbed 39% between 2001 and 2002.

Need for Research

Dr. Douglas Bunnell, psychologist and president of the National Eating Disorders Association, offered to facilitate our adult support group because he, too, developed Lyme disease. Dr. Bunnell is quick to point out, for this article and at every meeting, that the group represents a skewed sample of patients. We tend not to see those who have recovered. Still, significant numbers develop ongoing symptoms despite standard treatment. Why? In his own case, Dr. Bunnell developed a bull's-eye rash he recognized immediately. He received two weeks of antibiotics, a common prescription in 1993. Despite early detection, he later found himself in the emergency room with Lyme meningitis.

Although Dr. Bunnell is not sure antibiotics are the ultimate answer (noting other therapies might alleviate symptoms), he feels treatment is more likely to be inadequate than excessive. Unfortunately, he says, the efficacy of different regimens is contested: some physicians insist four weeks is adequate, while others see the necessity in some cases for years of treatment. Unless a foolproof test is developed—to assess both infection

In This Issue

Beyond the Bull's-Eye: Advocates Take Aim at Lyme Disease	1
Hearing Voices: Critical Underpinnings for Health Advocacy in a Complex World	2
Medical Errors: The Role of the Patient Representative	3
What's a HAP Intern Doing in a Maximum Security Prison? Teaching...and Learning.....	5
Breast Cancer Survivor Influences Research and Public Policy Processes	8
Developments in Human Research Protection	10
A Friend in Need: How a Small Program Can Make a Big Difference.....	14
New HAP Group Focuses on Health Policy	15
Working Together To Improve the End-of-Life Experience	16
Communicating with Children and Adolescents with Life-Limiting Conditions: A forum co-sponsored by the Health Advocacy Program and the Westchester (NY) End-of-Life Coalition.....	17
From the Director	19

Continued on page 7

Hearing Voices: Critical Underpinnings for Health Advocacy in a Complex World

By Rachel Grob

"I've 'found' my voice, then, just where it ought to have been, in the body-warmed breath escaping my lungs and throat.... The voice is the creature of the body that produces it."

"I think it was [a] sense of commonality with others I didn't even know...that urged me to write that first essay, not merely speaking out but calling out, perhaps. 'Here's the way I am,' it said. 'How about you?' And the answer came... 'Me too! Me too!'" —Nancy Mairs¹

What most distinguishes the health advocate from other professionals is our attentiveness to "voice." We attend to the experiences and perspectives, needs and strengths, history and aspirations individuals bring to bear on their health and their health care. We analyze the ways "voice" is heard, silenced, ignored, answered within the care systems and social structures that frame health and illness. We design and implement interventions intended to make health providers and systems more responsive to the deeply-felt, personal, embodied experience of those needing care. We listen hard for harmonies, for choruses that tell us about common experiences, about what matters to many, with their emphatic "me too."

As a faculty, we also challenge our graduate students to begin finding their *own* voices as professional health advocates who work on behalf of others. What could be more fruitful, then, than a Health Advocacy Program faculty retreat devoted to "voice"?

When we gathered for our half-day retreat on June 5, 2003, we had already

¹From "Carnal Acts," in Foster, Patricia, *Minding the Body: Women Writers on Body and Soul*. New York: Doubleday/Anchor, 1994.

read a collection of articles related to voice, ranging from personal narratives to political analyses. Discussions were rich, broad-ranging and—as you might expect with a faculty as diverse in experience and disciplinary perspectives as ours—at times quite heated.

Themes included:

- Illness narratives—the patient's and/or caregiver's voice in defining feeling, meaning and experience of illness.
- Giving, enabling and appropriating voice—how can and do experiences move from the private to the public sphere? How are consumer/patient voices used in program development, implementation and evaluation, in the political process, and beyond? Who shapes the voice of a constituency? What are the ethics of harnessing voice for strategic purposes?
- Using the particular to understand the universal—voice as a "model of knowledge," an alternative to scientific ways of knowing.

The retreat generated many rich ideas for curriculum development in and between courses. We also began working on a prototype interdisciplinary seminar or workshop presentation on voice that we can take out into the community.

From the Editor

Advocacy is about voice—attention to voice, seeking a voice, finding one's voice, having a voice, raising one's voice. The articles in this issue reflect the tremendous range of voices speaking about and on behalf of health-related issues—from private to public, individual to institutional, local to national, theoretical to pragmatic. Recently, there has been a heightened focus on voice in the sense of personal narrative and, as Rachel Grob's article notes, the Health Advocacy Program is in the process of developing curriculum and community outreach around it. Future *Bulletins* will explore this initiative in greater depth.

As 2003 draws to a close, we health care advocates may find ourselves disheartened by the shifting governmental, political and economic landscape...the dismantling of established programs and protections...the postponement, dilution or abandonment of promises. This is not the time to lose our voices, however. It's the time to form a chorus!

—Lucy Schmolka

Perhaps most important, the retreat was an opportunity to continue our own reflexive practice as health advocates. We have intertwined obligations as advocates—to continually strengthen our own voices while, at the same time, listen carefully to others. And we have a collective responsibility to work on behalf of others, even when our initial response to them is "not me!" rather than "me too!" For me, the afternoon of "hearing voices" was an exercise in developing the kind of sanity and wisdom we need as advocates in a poly-vocal world, and as faculty in a poly-vocal classroom.

For a copy of the bibliography developed for the retreat, contact Crystal Greene in the HAP office at (914) 395-2371 or cgreene@sarahlawrence.edu.

Rachel Grob, HA '92, is SLC Associate Dean of Graduate Studies and co-teacher of the HAP course Models of Advocacy: Theory and Practice. ■

<http://slc.edu/~health>

The HEALTH ADVOCACY BULLETIN is a publication of the Health Advocacy Program at Sarah Lawrence College, One Mead Way, Bronxville, New York 10708.

Editor: Lucy Schmolka, MA.

Program Director: Marsha Hurst, PhD.

Production: Riverside Resumes

Email: health@slc.edu

All material in the HEALTH ADVOCACY BULLETIN is the property of the authors and may not be reprinted without permission. Opinions expressed are not necessarily those of the editor nor of the Health Advocacy Program.

Medical Errors: The Role of the Patient Representative

By Laura Weil

Patient Advocacy in the health care institutional setting often includes ensuring that patients receive complete and comprehensive information, enabling them to make informed decisions about treatment options. Sometimes the advocate's intervention derives from other imperatives. In situations where medical errors have occurred, the advocate must make certain that the risk-averse position of health care institutions does not obstruct patient knowledge of the facts. The potential for a patient lawsuit should not inhibit providers from being promptly open and forthright when a medical error takes place. The advocacy intervention involves making sure that the patient receives all relevant information, and assuring that the institution investigates and acknowledges the causes of the error and uses the information for effective corrective action.

Let us define medical error as a commission or omission with potentially negative consequences for the patient that would have been judged wrong by other skilled clinicians at the time it occurred. There are two kinds of errors.

1. *System errors*, sometimes called *latent errors*, are caused by flaws in processes or policies that result in harm to the patient; e.g., the continual unavailability of prior medical records causes a patient to be given a drug to which he had an adverse reaction in the past.

2. *Individual errors* result from a deficiency of the provider's knowledge, skill or judgment; e.g., prescribing a drug for which the patient has known contraindications.

Many physicians believe that patients do not really want to be informed about errors, especially if they result in no change in outcome. This belief is not necessarily based in self-protectiveness. There is a substantial group of patients who, when ill and frightened, prefer a paternalistic physician model. The authority and extraordinary knowledge of the all-powerful physician figure give them the confidence to submit to terri-

fying treatment regimens, bolstered by the belief that such confidence and hope will have a positive effect on treatment outcomes. Some people truly do not want to know that physicians are not infallible. However, studies show that a majority of patients prefer to be informed about errors, even if this degrades their belief in the all-knowing physician figure. The discrepancy between patient preferences and physician beliefs is significant:

- 98% of patients want to be informed of even minor errors, and, when severity of error is factored in, the percentage of those wanting to know increases;¹
- 92% of patients believe they should be told of errors; only 60% of physicians believe that patients should be informed;²
- 81% of patients believe they should be told about possibilities of future implications of error; only 33% of physicians believe that they should discuss possible future implications.³

What is the role of the patient representative/patient advocate—an employee of the institution—when a patient is harmed by a medical error? While the role may be circumscribed by institutional policy, the advocate has a primary responsibility to the patient to assure that his/her rights are respected.

Case Study: a patient is the victim of a system error requiring subsequent hospitalization

In this study, the role of the patient representative was twofold:

1. To provide emotional and logistical support to the patient and his family.
2. To act as the "conscience" of the institution, making sure that the clinicians and administrators involved provided honest and complete disclosure regarding the error that occurred, its potential sequelae to the patient and the corrective action taken to prevent recurrence.

Mr. J is a 67-year-old male with a history of hypertension, non-insulin-dependent diabetes, coronary artery disease and arthritis. He is retired and lives with

his wife and adult daughter. He came to the hospital for an ambulatory arthroscopic procedure for knee pain. He tolerated the surgery well and was discharged to his home the same day.

Shortly after his discharge, operating room staff discovered that the tray of instruments used in Mr. J's procedure had not been through the complete sterilization process. The error was reported to the administrator on call, who reported the incident to risk management and then requested the assistance of the patient representative.

The advocacy issues

1. Identify and act on the patient's needs, including the need for accurate information.
2. Investigate system issues that led to the error.
3. Design corrective action to prevent recurrences.

A multidisciplinary team was assembled a few days later and conducted a root cause analysis of the contributory processes to address items 2 and 3. Changes in process were implemented, including change of storage area for trays that are not yet completely sterilized, a change in staff responsibilities for moving trays to the OR, and identification of specific role responsibilities for redundant checks on tray and instrument sterilization status. While the patient representative participated in and monitored the above process, her primary responsibility was to address the patient's specific needs.

Clinical needs

As soon as the error was identified, Mr. J was called and informed that, because of an error in the operating room, he was being asked to return to the hospital as soon as possible. When he arrived, accompanied by his wife, the orthopedic surgeon, the patient representative and an infectious disease physician were on hand to greet him. He was understandably anxious, and received a brief but honest explanation of the fact that he was possibly exposed to infectious material via incompletely sterilized

Medical Errors: The Role of the Patient Representative

Continued from page 3

instruments used in error, and it was recommended that he remain in the hospital for a few days to receive antibiotic and antiviral therapy. He agreed to do so.

Mr. J was very passive, did not ask many questions and was admitted directly to the floor. He was clearly frightened. Prophylactic IV antibiotics were started immediately. He and his wife were given the patient representative's card and encouraged to contact her with any questions or needs. Mr. and Mrs. J seemed unwilling to engage in discussion of the incident. The patient representative stayed in touch with them during the hospitalization, throughout which Mr. J was quite ill from effects of the medications—antibiotics, hepatitis vaccines and anti-retroviral drugs to prevent HIV infection.

Immediate investigation determined the identity of the patient on whom the incompletely sterilized tray had been used previous to its use on Mr. J. This patient was contacted, provided with a brief explanation and asked to come to the hospital for testing for HIV and hepatitis. She agreed to do so. However, all attempts to have her actually come for testing were unsuccessful.

Facilitation of information and logistical support

During the hospitalization, the patient representative was available to provide support to Mr. and Mrs. J. At discharge, the patient was asked if he had any further questions about the incident. He said he was still feeling too ill from the medication to address the matter at that time but agreed to call the patient representative when he was feeling better. Charges for the hospitalization were waived. Voluntary physicians (those not salaried by the institution) who cared for the patient agreed to hold bills.

After discharge, Mr. J contacted the patient representative: He had called his orthopedic surgeon with various physical complaints, concerned that they might be related to the incident. At a scheduled follow-up appointment in the orthopedic practice, he was seen by a different physician and felt that he was being given "the brush-off" by the original surgeon. Mr. J also expressed concern about the long-term health effects of both exposure to non-sterile instruments and medications taken to prevent infection. He was

clearly ready for more information. The patient representative offered to set up a meeting where he could have all questions addressed in an open forum. Mr. J was agreeable, but his wife conveyed understandable skepticism that any truthfulness would be forthcoming.

The patient representative facilitated the meeting. It was made clear to participants that its purpose was to address honestly and openly what had happened and the implications for the patient. The orthopedic surgeon expressed fear of a lawsuit.

Mr. and Mrs. J, the chief physician for infection control, the nursing director for operating room services, the medical director (the institution's chief medical officer) and the patient representative attended the meeting. The orthopedic surgeon was absent, having initially agreed to be there. Complete details about how the error occurred were given to Mr. and Mrs. J, including the series of events that led to an incompletely sterilized instrument tray being available for use. The chief of infection control provided a step-by-step explanation of the sterilization process, explaining that the last step was omitted in this case. The new procedure, since implemented to eliminate the possibility of a recurrence, was outlined. The rationale for the prophylactic drug treatment plan that was followed was explained. The fact that the patient on whom the tray was used previously was not considered at high risk for either hepatitis or HIV was disclosed to the patient, as well as the unsuccessful attempts to have that testing done.

The medical director answered all questions honestly and thoroughly. He accepted full responsibility, on behalf of the institution, for the error. Mr. and Mrs. J acknowledged a better understanding of the events and subsequent treatment, and expressed gratitude for the honesty and sensitivity with which the information was provided. The medical director coordinated appointments with clinicians to address specific symptoms. Mr. and Mrs. J were encouraged to speak with the patient representative about any further needs or concerns.

Over the next several months, Mr. and Mrs. J occasionally called the patient representative with requests for assistance. When the patient was admitted via the Emergency Department for an unrelated issue, Mrs. J contacted her for facilitation and help. Later, the patient came to the hospital for another ambulatory proce-

dures. Mr. J did not call to ask for patient representative aid. Mrs. J called the patient representative afterward to report satisfaction, which was intended and received as an expression of renewed trust in the institution and the care rendered.

This intervention was successful because the institution's leadership was willing to provide complete disclosure, despite the unwillingness of the individual practitioner (who ironically bore no responsibility for the actual error) to participate. Advocacy in the institution is a collaborative enterprise and works best when the patient advocate motivates or potentiates the participation of many players at many levels to do what is right for the patient.

Why Disclose Errors?

Hospitals are required by a variety of regulatory authorities, including the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and state statutes, to disclose medical errors and unanticipated outcomes to patients. Generally, the requirement is triggered when patients are substantially harmed, which would include all patients who require additional treatment or hospitalization as the result of an error. Institutions consider that harm is the prompt for disclosure.

In addition to statutory and regulatory imperatives, physician organizations have clearly stated that there is a professional obligation to inform patients about errors:

- *American College of Physicians Ethics Manual*: "Physicians should disclose to patients information about procedural and judgment errors made in the course of care, if such information significantly affects the care of the patient."
- *AMA Council on Ethical and Judicial Affairs*: "Situations occasionally arise in which a patient suffers significant medical complications that may have resulted from the physician's mistake or judgment. In these situations, the physician is ethically required to inform the patient of all facts necessary to ensure understanding of what has occurred."

Discussions of errors based merely on regulatory standards may not lead to productive dialogue between care-giver and care-receiver. The motivation must include a moral commitment to the patient's fundamental right to information. In the hospital setting, institutional

What's a HAP Intern Doing in a Maximum Security Prison? Teaching...and Learning

By Pat Stanley

Harris Road begins in Bedford Hills and ends in Bedford. It bisects some of the most beautiful land in Northern Westchester and is flanked by expensive estates and horse properties. Less than half a mile in on the Bedford Hills side is New York State's only maximum security women's prison, the Bedford Hills Correctional Facility. The brick buildings, completely visible from the road, are clearly off limits, enwrapped in razor wire and anchor fencing 15 feet high. This formidable place was the location for my first HAP internship. I was a teacher's assistant to Dr. Charlotte Price, a retired Sarah Lawrence economics professor, and last spring we were going to teach economics for the first time in the college program at the prison.

Teaching the Course

As Charlotte and I arrived for our first class, I could not help noticing the dramatic contrast between the luxurious setting and the stark prison entrance, a concrete-block building with its odd overhanging security tower, set in the middle of an acre of pavement cordoned off by the ubiquitous fencing. It took 20 minutes for the initial security check at the gate before our entry into the prison itself, which began with an uphill walk to the main building that housed our classrooms. A second sign-in and officer check and we were through barred doors to still another screening. Finally, after entering five barred doors and displaying our fluorescent-stamped hands three times, we reached our classroom.

The classroom was unremarkable and we were able to fashion a circle of chairs to simulate the round-table effect at SLC. We both carefully put our belongings close to our own chairs as instructed by the volunteer office. Eventually the class filed in, until 14 women dressed in green sat in the circle with expectant faces turned towards us. After introductory remarks, Charlotte began teaching from the text. During a section on the rudiments of bar graphs, one student pointed out that the graph did not illustrate what the text had explained. Charlotte turned this embarrassment into a positive by saying that it was not uncommon for

errors to occur in a textbook and promised to send a letter to the publisher noting that a student had noticed an error on her first day in economics class!

My role was to supervise the students' research papers (each 10-15 pages) by suggesting topics and providing research material. Since students do not have access to the internet or to an extensive library, everything has to be brought in from the outside. I began by suggesting six possible subjects with a health theme. As the weeks progressed, I had 13 different topics to research, including global warming, the abuse of third-world countries by multinational corporations, the reason that every American does not have the same health insurance as President Bush, the politics and economics of choice on childbearing, the Draconian Rockefeller Drug Laws, and the criminalization of the mentally ill. Although I had been cleared to bring in articles, books and newspapers, I pushed the weekly quantity to the max. It always took me longer than any other teacher to get through security, since the officers are required to inspect each folder and book.

One student decided she would like to explore why the American pornography industry has revenues exceeding all professional sports combined. I enthusiastically agreed to begin work finding material. In addition to reams of internet articles, I found an excellent book entitled *The History of the Pornography Industry*. The day I went through security with that material was noteworthy for both the additional time and the officer's raised eyebrow when he pulled out the book. I put on my best poker face, and he put the book back in my bag without comment. A few weeks later, the inmate who had selected this topic, and who was by now knee deep in research material, came to me a bit chagrined. She had to change her topic. When I asked why, she confessed that she was in prison for a sex crime and that it would not be in her best interest if a stash of porn research were found in her room by the officers. I tried not to look nonplussed and simply suggested that we find her another topic immediately. "How about affirmative action?"

This story points to one of the most difficult aspects of teaching at the prison.

As an outsider, one is not privileged to know any background on the inmates, nor is one allowed to ask. Teaching economics is particularly hard without a relevant context in which to illustrate major themes. Both Charlotte and I struggled with this problem, until we were clued in by some outspoken inmates who demanded that we make the theory pertinent to their lives. They helped us by giving examples from within the prison, such as the economics of the commissary and the prison wage system. One of the most difficult areas for them to understand was taxes; I am not sure any of them had ever paid any. The flip side of this anonymity is positive for the inmates, who sit in class knowing that they are not prejudged by their individual pasts.

Teaching at the prison last semester meant we were faced with interruptions caused by bad weather and national orange alerts that necessitated closing the institution to outsiders. One alert caused us to miss four weeks in a row. Fortunately we were able to schedule make-up classes into June, but the uneven rhythm of teaching and learning made for much review work. Further hardships were caused by the limited hours that the word-processing computers were available (they were located in the learning center, which is staffed entirely by outside volunteers), schedule conflicts between prison work and school, demands on the inmates' time to work on their court appeals, family overnight visits which often resulted in absences from class the day of and after, and health and medication problems. The only student who dropped out did so for health reasons. Outweighing these negatives was the outstanding attitude of most of the inmates. Although diverse in educational preparation and approach, they all really cared about doing a good job. Charlotte noted that, after 30-plus years of teaching, she thought this class was a particular joy to teach.

One of our best classes was based on a discussion of Eric Schlosser's book, *Fast Food Nation*. All of our students had worked in fast food restaurants and engaged in a lively discussion of the characteristics of each one. Wendy's was voted unanimously as the best, KFC the worst. I now have many tips on what

What's a HAP Intern Doing in a Maximum Security Prison? Teaching...and Learning

Continued from page 5

time of day to order a burger and how to tailor it to be freshly cooked! One student remarked on the taste difference between a McDonald's hamburger served in Jamaica and one in England, which prompted a discussion of international marketing and how products are tailored to a specific population.

Each week we had a current events discussion, which usually centered on President Bush's budget and national policy. The class leaned heavily to the left of center. One student, a rabid Marxist, held forth weekly in defense of the poor; another lectured on the destruction of the environment by capitalism; and several railed against multinational corporations and sweatshops. At times, the volume of noise was so high with laughter and anger that the students in the psychology class next door were envious of our lively exchange. At no time did we feel threatened by our students. They were always respectful to us, and, upon exiting the classroom, wished us a safe trip home and a nice weekend.

Graduation

The highlight of the semester was graduation. From the moment we entered the gate and walked past a line of 20 or so visitors, I knew it was going to be a special day. Superintendent Elaine Lord was helping to clear "staff" visitors, checking our names off the list and stamping our hands. I assume she was doing this to help the officers with the unusual burden of so many visitors at one time, an example of her inordinate caring for both staff and inmates. Graduation is a special privilege of this institution. No other maximum security prison has a college program, and its existence at Bedford is partially due to this extraordinary woman. We cleared very quickly and, in only five minutes, we found ourselves on the flower-lined path which led to the building where we taught. The razor wire glistened in the bright sun and we remarked how Mother Nature was in sync with the celebratory spirit of the day.

After completing the rigorous sign-in ritual, we found ourselves in the hall bordering the classrooms. The usual silence was replaced by sounds of joyous hysteria, and we quickly joined the merriment in one of the rooms. Students in colorful robes were everywhere, in varying states of getting dressed, applying makeup, fixing hair. Charlotte had worn her pale-

blue Columbia robe, complete with hood and velvet hat. When one student saw her, she exclaimed, eyes wide with admiration, "WOW! Look everyone—this is *my* professor, Dr. Price." This student had graduated from the two-year program the previous year and was on the graduation committee. She had ironed all 81 robes and hoods for the ceremony and was in the room enthusiastically assisting everyone.

In another classroom, coffee and donuts were set out for visiting dignitaries, presenters and guest speakers. I chatted with Judson Shaver, President of Marymount Manhattan College, who had brought two other deans from his college for the occasion. His strong and unflagging support of the program is a key to its success, since Marymount Manhattan is the undergraduate-degree-granting institution. I had a chance to meet with other teachers, most with doctorates, an impressive group in their multicolored robes and hoods. We traded fond stories about the students as we waited for the proceedings to begin. The consensus: it was a privilege to teach these women who were desperate to learn and improve themselves.

It was an incredible experience to march into the gym filled with rows of graduates, tables and chairs for families and "bleacher seats" in the rear for inmates, staff and more visitors. At least 30 dignitaries graced the stage. Hoots, hollers and intermittent cries of recognition rang out over the tinny broadcast of "Pomp and Circumstance." We filed in to fill whatever chairs were assembled directly behind the 81 graduates, some of whom had completed high school, some vocational and apprenticeship programs, some college and, for 15 students, their master's degrees. This was the largest class of graduates in the history of education at BHCF.

Charlotte and I ended up seated behind the family members of one of our most fragile students. They had driven from Buffalo to witness the event. This student has three children, the youngest of whom is seriously ill and in need of a kidney transplant. She looks very much like her mother, although painfully thin. The older daughter had a photo of her mother taken in her robe which she placed on the table and fingered throughout the ceremony. The grandfather, surrogate caretaker of the children, occasionally provided a secure arm to comfort her and remained

proudly attentive during the two-hour ceremony. The middle child, a boy, was very quiet and seemed detached from the proceedings. As I looked around the room, most of the guests were women and children. Apparently men generally do not visit their women in prison. (The reverse is true for incarcerated men.)

One noteworthy aspect of this graduation was the overwhelming ratio of staff, graduates, teachers and presenters to visitors. Perhaps the burden of having to travel a long distance on a workday proved too much for many family members. The 20 or so non-graduating inmates who were allowed to attend all wore starched and pressed white shirts instead of the usual green. This formality was a testament to the pride all the women could share in the achievements of their fellow inmates.

The speakers welcomed and praised the graduates for their perseverance in "striving for excellence, above and beyond." President Shaver's message included allusions to two famous incarcerated individuals, Nelson Mandela and Martin Luther King. A'Lelia Bundles, great-great-granddaughter of Madame C.J. Walker, the first female African American millionaire, gave an impassioned address that included a crescendo of exhortations more reminiscent of her ancestor's reputation as a "race agitator" than of her own job as a TV journalist.

Superintendent Lord spoke warmly and with great inspiration (and an occasional tear), encouraging the graduates to continue their quest for self-improvement once outside the walls of Bedford. Michelle Daniels, a former inmate who now works at Manhattanville College, transformed the gym into a gospel hall with her rendition of "Eye on the Sparrow." Four graduates spoke as salutorians or valedictorians, delivering speeches that rivaled any I have heard from their counterparts on the outside. One of our students was salutorian for the bachelor's degree. Her eloquent remarks, spoken through tears, made me feel proud to have known and taught her.

Watching the graduates mount the stage to receive their diplomas or certificates was equally stirring. Some managed to camouflage the Bedford green wearing their long robes with stockings and high heels (red, black, clunky, stiletto—even a pair of gold boots). Others strode to the stage in sneakers, green pants hanging beneath their robes. Some brought their young children with them as they

Beyond the Bull's-Eye: Advocates Take Aim at Lyme Disease

Continued from page 1

and cure—the controversy will continue.

Brian Fallon, MD, MPH, M.Ed. (Associate professor of clinical psychiatry, Columbia University, and Director, Lyme Disease Research Program, New York State Psychiatric Institute), agrees a definitive test would quell the debate. While most infections are easy to culture, the bacterium responsible for Lyme disease—a corkscrew-shaped spirochete—is more elusive. Doctors rely most often on antibody tests, such as the ELISA and Western Blot, which measure the body's response to an infection.

But results vary from lab to lab. Dr. Fallon says a single blood sample may be positive according to one lab, but negative according to another—a phenomenon that has been studied by the National Institutes of Health but is not widely known by doctors.

The CDC recommends two stages for testing. The ELISA comes first; if results are positive or equivocal, the Western Blot is next. But does the ELISA have the sensitivity needed for screening? A significant number of patients are negative on the ELISA but positive on the Western Blot. Interpretation of the Western Blot is also problematic. The CDC has established a standard that is debated by researchers and laboratory directors. Dr. Fallon thinks these disputes, too, are unfamiliar to many clinicians.

Tests administered at the first sign of a bite or rash may be negative, since antibodies need time to develop. Diverse immune system responses, antibiotics received prior to testing and bacterial strain variations may also affect outcomes. Both false positives and false

negatives are possible. It is essential to consider that ticks are now known to harbor other illnesses such as babesiosis and ehrlichiosis. One tick may even carry two or more infections. Since testing for emerging pathogens is also unreliable, diagnosis is likely to become more troublesome than ever.

Diagnosis

According to the CDC, Lyme should be diagnosed on the basis of clinical symptoms. Lab tests may support the doctor's conclusions, but should not decide the matter. Nevertheless, Dr. Fallon has seen doctors rely exclusively on negative results from one lab, even with clear-cut clinical evidence to the contrary.

Without a bull's-eye rash, what difficulties do patients encounter in the diagnostic process? Disseminated Lyme can affect many systems in the body. Dr. Fallon says this may be problematic when patients visit specialists, who tend to concentrate on symptoms that fall within their realm of expertise. Patients with multiple complaints—and Lyme can affect the brain, heart and musculoskeletal system, among other things—may struggle to find a doctor who recognizes a possible interrelationship. In addition, Lyme's multi-systemic nature makes evaluation extremely time-consuming. Insurance constraints may leave physicians little time to unravel a medical mystery.

Basic signs may well be missed or misinterpreted. Lyme rashes do not always form a bull's-eye and may be identified as spider bites or fungal infections. Even classic rashes are easily overlooked when they present on the scalp or back. Late-stage Lyme has many variations

and may be confused with numerous illnesses. Support group attendees have been diagnosed with multiple sclerosis (MS), arthritis, chronic fatigue syndrome, fibromyalgia, early menopause, Alzheimer's disease, psychiatric illness or ADHD before finding relief under the care of Lyme specialists.

Paige

In October, 1999, while taking a shower, 12-year-old Paige noticed an odd rash. She didn't think much of it. Her mom, Marcy, thought it was a simple insect bite, nothing to worry about. Three months later, Paige found herself with a sore throat, a stiff neck, flu-like symptoms and a massive headache. Because a strep test was faintly positive, her doctor administered antibiotics. Paige is prone to strep and usually recovers quickly. This time she didn't improve. She was in terrible pain, confined to a dark room, acutely sensitive to light. Her doctor tried other antibiotics, and eventually some of her symptoms subsided. But the headache, stiff neck and fatigue "just wouldn't quit." A CAT scan of her sinuses was clear; the next step was a scan of the brain. Marcy and her husband Andrew were "flipping out," since doctors were looking for a tumor. That test, too, was negative. Next, a neurologist diagnosed migraines due to muscle spasms in the neck. He was not willing to pursue the matter further, nor would he return Marcy's calls. Their pediatrician thought Paige must have a post-viral syndrome and said he was out of options.

Marcy felt abandoned by the doctors, afraid "no one really cared." Paige had

Continued on page 8

What's a HAP Intern Doing in a Maximum Security Prison? Teaching...and Learning

Continued from page 6

climbed the steps to shake hands with President Shaver, basking in the glory of their achievement as models for the next generation. One woman who received the Thea Jackson Award threw her arms up in the air and proclaimed, "This is for my mother!" As her mother came forward from the audience to join her, I was not the only one wiping away tears. (Thea Jackson is the community leader who spearheaded the drive to form a consortium of regional colleges to continue the college at Bedford as a privately funded

program after Pell grants for incarcerated students were cut in 1994.)

The ceremony concluded with each group of graduates moving its tassels from the right to the left side of its mortarboards. Then they sat down having joined a long legacy of educated women. I could not help but reflect upon the future for those inmates who had completed their master's degrees yet were facing many more years in prison. As one valedictorian remarked, "We are women who have decided to believe in ourselves and in our worth as human beings." For now that will have to be enough.

As a teacher, I became an advocate for "my women on the inside" to anyone who would listen on the outside and a campaigner for education in the prison. Advocacy for prison reform is no different from advocacy for patients' rights. Consciousness-raising becomes the *modus operandi*—and caring enough to get involved.

Pat is about halfway through the HAP. She is currently interning at Columbia College of Physicians & Surgeons, where she is associate coordinator for an NEH grant in Narrative Medicine. ■

Breast Cancer Survivor Influences Research and Public Policy Processes

By Jane Baker Segelken

The scientists liked—appreciated, really—what we had to say. Imagine the thrill of being told by a highly respected breast cancer researcher that your perspective counts. That's exactly what happened last August when I served as one of three consumer/advocate reviewers for the Department of Defense (DOD) Congressionally Directed Medical Research Programs' breast cancer proposal review in the immunology section. "You helped us remember that human beings are affected by the work we do," a scientist from Missouri said. "Only someone who has been directly affected by breast cancer can bring the appropriate perspective to this process. Your point of view is something we desperately need."

The Road to Activism

My journey to the DOD (and the Susan G. Komen Foundation, where this fall I served as an advocate reviewer in the tumor cell biology section) began seven years ago when I was diagnosed with breast cancer, just two days before my 42nd birthday. Many people have heard me say that experience made me a strong self-advocate. Some know me as a diligent volunteer who has worked to ensure that others have the kind of support I was so generously given. Throughout, I've sought activities that would allow me to help on a broader level.

I educated myself in the language of breast cancer and gained an understanding of how decisions are made. Volunteering with the Ithaca Breast Cancer Alliance and participating in the New York State Breast Cancer Network

helped me learn about the issues of importance in my community and region; attending the National Breast Cancer Coalition (NBCC) annual meeting and visiting representatives on Capitol Hill gave me a national perspective. Three years ago, I completed the NBCC's Project L.E.A.D. (Leadership, Education, Advocacy and Development), a science-training course that gave me the information I need to help influence research and public policy processes.

Modus operandi

"Oh, my God! What have I gotten myself into?" Advocates and scientists were scheduled to convene in Virginia to collectively review research proposals written to address prevention, detection, diagnosis and treatment of breast cancer. Several weeks before the meeting, I received a huge box containing the 14 proposals for which my team—two scientists and myself—were responsible, along with detailed instructions on how to conduct the evaluation. Another consumer reviewer was supposed to mentor me, but, except for one brief conversation, he was basically incommunicado. A scientific reviewer was available to answer questions, but I didn't even know what to ask. Our instructions were clear: No discussion of the proposals could occur with anyone before the panel convened. I was totally on my own.

Once I was brave enough to actually look at the proposals, my heart began to beat normally again. My job was *not* to evaluate the science (consumer reviewers were to presume the science was correct), but instead to provide insight from my personal experience and those of oth-

ers with whom I worked and volunteered. I was the "voice" of the survivors, their families and those at high risk for getting breast cancer.

Over two days, 3 consumer/advocate reviewers and 15 scientists listened to comments and justification for the score we had given each proposal. Questions were asked and clarifications were made. We could even change our scores if we believed they needed adjusting after the discussion. I learned from the scientists details only they could provide; from me they received fine points that only a breast cancer survivor can impart. The DOD procedure is what it claims to be—a comprehensive review that includes consumers in the decision-making process. I actually witnessed instances in which my comments helped influence the final decisions.

The DOD?

We can all understand why the Komen foundation, the American Cancer Society and others fund breast cancer research. But why is the Department of Defense funding it? The office of Congressionally Directed Medical Research Programs, established in 1992, manages Congressional Special Interest Medical Research Programs that include breast, prostate, and ovarian cancers, neurofibromatosis and military health.

The inclusion of breast cancer research was the result of much lobbying by breast cancer advocates who believed that one reason for the slow progress in breast cancer treatment is that grants tended to go to the same scientists and institutions that researched the same tac-

Continued on page 18

Beyond the Bull's-Eye: Advocates Take Aim at Lyme Disease

Continued from page 7

by now missed weeks of school (her mother, a psychotherapist specializing in chronic illness, had stopped working to care for her). She went on to experience episodes of disorientation and confusion. A gifted, well-organized student, she tried her best to attend school. But she missed so much she had to be tutored at home. Paige began losing

things and forgetting assignments. She developed numbness, light sensitivity and other "weird" symptoms. Her parents were worried and exasperated by memory issues they did not understand. Marcy says, "When she was ...forgetting to bring her books home...we didn't realize it was from the disease, so we were fighting....I'm sure people diagnose ...behavior problems that have nothing to do with behavior;

they have to do with cognitive deficits."

An old friend suspected Lyme disease. At Marcy's insistence, despite the pediatrician's objections, Paige was tested. Her ELISA was positive and antibiotics were prescribed. Shortly afterwards, though, a negative Western Blot arrived. The doctor concluded Paige must not have Lyme and asked Marcy to discontinue the medicine. Marcy, however, read the lab report, which

Continued on page 9

Beyond the Bull's-Eye: Advocates Take Aim at Lyme Disease

Continued from page 8

stated Lyme should be diagnosed clinically, not on the basis of test results. She kept Paige on antibiotics and consulted several specialists. All denied the possibility of Lyme, providing other diagnoses including depression, chronic fatigue syndrome and MS. Marcy, whose profession required knowledge of all these illnesses, was positive Paige did not have them. As a psychotherapist, she was also quite sure Paige was not depressed.

Four months after Paige became ill, her parents found a doctor who interpreted the Western Blot quite differently. In his opinion, her symptoms and even her lab testing pointed clearly to Lyme disease. He convinced Paige's pediatrician to begin intravenous (IV) antibiotic therapy. She had an intensely difficult initial reaction. (Many support group members report feeling worse during treatment. This phenomenon occurs because, as bacteria are killed, they release toxins. Marcy says, "I felt like I was having an exorcism in my house.") Paige had seven weeks of IV and three months of oral antibiotics. Three years later, she remains symptom-free. "Since hearing our story," Marcy says, "I can't tell you the number of people who've come out of the woodwork with horror stories about their father, their uncle, their little boy."

Neurological and Neuro-Psychiatric Effects

Dr. Fallon estimates that, even in Lyme-endemic areas, 75% of doctors are unaware Lyme may mimic MS and other neurological conditions, although severe neurological complications caused by similar spirochetes are well established in European medical literature. Syphilis, another spirochetal infection, has been known for decades to incite neurological symptoms in untreated patients. Studies conducted by Dr. Fallon himself have examined the connections between Lyme and several neurological and psychiatric conditions, including depression, ADD, autistic-like syndromes and many cognitive and memory disorders.

Jane

In 1990, Jane, a pediatric intensive care nurse, woke from sleep and realized "I could not feel the right side of my body at all." She was tested for Lyme among other things; her ELISA was negative,

and her neurologists diagnosed a post-viral syndrome. She lost seven weeks of work. In 1993, she had another episode: this time, she could feel nothing from the chest down, her speech was slurred, her vision was blurry and she had word retrieval difficulties. An MS verdict was issued following a brain MRI. Years later, Jane saw a copy of the MRI report and was shocked to discover Lyme mentioned as a possible cause. Jane had never been informed of this possibility nor sent to a specialist. Numerous symptoms continued to plague her. In 1997, an acquaintance mentioned her illness resembled Lyme disease. Although tests were equivocal, Jane received 7 1/2 weeks of IV antibiotics and follow-up orals. Her neurological manifestations diminished, although some flared later and were retreated.

Once Jane discovered she might have Lyme, she wondered whether her son, whom she had carried while symptomatic, might have acquired Lyme congenitally. He had been placed in special education at age two when diagnosed with Asperger's syndrome (a developmental disorder in the autism spectrum affecting communication and socialization). Jane had him tested for Lyme; his results, like hers, were equivocal, and he was treated. Eleven months of antibiotic therapy dramatically improved his ability to socialize. One year later, he was fully mainstreamed with minimal assistance.

Jane was unable to work during her thirties because she was afraid her recurring cognitive problems would endanger her patients. Happily, she now considers herself cured. "It's part of the Hippocratic oath to keep up with research," she says, "and it was all over the research in the 90's that Lyme... produces an MS-like illness....Hey, if I can find it in the research, why can't the doctor?"

Depression

Depression may be the most common diagnosis support group members receive prior to learning they have Lyme. Dr. Fallon says distinguishing between the two may perplex doctors without psychiatric training. Depression has physical features—such as fatigue and sleep disturbance—that characterize several illnesses, including Lyme. Without a definitive test, diagnosis may be confounding.

To complicate matters, depression can occur on its own, as a symptom of Lyme,

as a result of Lyme-induced symptoms like fatigue and pain, or as a consequence of going from doctor to doctor for an explanation. Dr. Fallon also suspects Lyme may aggravate a predisposition to psychiatric conditions.

Assessment may be further confused by emotional factors. Dr. Fallon says patients may arrive at his office feeling anxious or hostile because they have been "turned away, rejected or pushed aside" by other physicians. The last thing they want is to be sent to a psychiatrist. Others want a guarantee they have Lyme, which he cannot provide. He says patients may well be traumatized by doctors' reactions. Dr. Bunnell agrees: "If the doctor in whom you have placed your trust does not recognize your experience, if you arrive feeling powerless and sick and leave without acknowledgement you are ill, the results can be devastating." Without a doctor's support, family, friends and co-workers may also be skeptical, compounding feelings of abandonment.

Dr. Bunnell says Lyme patients may well be told to seek a psychiatric evaluation—a problem since "the eyes of subsequent doctors tend to go straight to this referral." Despite the growing awareness that "there's a tremendous physiological base we can apply to brain functioning," some doctors see depression as an underlying cause rather than as a symptom of physical illness.

Patients with Lyme tend to look well, adding to such suspicions. Drs. Bunnell and Fallon agree symptoms tend to wax and wane. Dr. Fallon has seen family members become enraged when loved ones attend work or school one day, but are bedridden the next. Such issues may profoundly alter relationships, says Dr. Bunnell—at home, at work and at school—especially without absolute proof the illness exists. He notes Lyme patients may not be excused from everyday expectations because they are not perceived as ill.

Memory and Cognition

As Paige's neurological symptoms progressed, her parents were able to serve as her advocates. Unfortunately, Lyme patients without advocates may find the diagnostic process further hampered by cognitive and memory impairment, symptoms Dr. Fallon's research has explored in depth. Patients can be disorganized when they recount their histories, even forgetting their own

Continued on page 12

Developments in Human Research Protection

Last summer, two HAP students, Marlene Krammer and Deborah Guiffre, attended the inaugural meeting of the Secretary's Advisory Committee on Human Research Protections in Washington, D.C. The first of the following articles describes the committee and its role, the second and third discuss issues of particular interest to their respective authors.

The Inaugural Meeting of the Secretary's Advisory Committee on Human Research Protections

By Marlene G. Krammer

There is no doubt that clinical research involving human subjects plays an indispensable role in the development of new pharmaceutical, surgical and medical device treatments for disease. Equally important, however, is the protection of these subjects from exposure to unacceptable risk and disproportionate burden, from lack of fully informed consent, and from their own unrealistic expectations and individual vulnerabilities. During the past five years, a series of alarming events has demonstrated the prevalence of clinical program deficiencies and the dangers inherent in clinical trials. These events included federal shutdowns of research programs at major academic institutions and veterans' medical centers due to regulatory noncompliance and the deaths of two clinical participants, Jesse Gelsinger at the University of Pennsylvania and Ellen Roche at Johns Hopkins.

It is against this backdrop that the Secretary's Advisory Committee on Human Research Protections (SACHRP) was formed to provide expert advice and recommendations to the Secretary of Health and Human Services (HHS) on issues related to the protection of human research subjects. SACHRP is the successor to the National Human Research Protections Advisory Committee (NHRPAC), which similarly advised HHS Secretary Donna Shalala during the Clinton Administration. SACHRP consists of 11 voting members, including the chair, who are selected by the Secretary from among individuals with experience in any of several disciplines pertinent to human subject protection or clinical research. Current SACHRP members include a bioethicist, a lawyer, the CEO of a clinical research association, practicing physicians, medical school professors and administrators, clinical researchers, institutional review board members, and, last, but certainly not least, a patient advocate. The Director of the Office of

Human Research Protections (OHRP) serves as the executive secretary of SACHRP.

In addition to voting members, SACHRP has non-voting ex-officio members representing the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Food and Drug Administration (FDA) and the National Institutes of Health, as well as various other agencies of the federal government. SACHRP was chartered on October 1, 2002 and held its inaugural meeting on July 22, 2003. The purpose of the inaugural meeting was to review the activities left unfinished by NHRPAC and to plan and prioritize SACHRP's activities for the next 24 months.

SACHRP's charter emphasizes its role in advising HHS on matters involving research on special populations (such as neonates and children, prisoners and the

decisionally impaired); pregnant women, embryos and fetuses; international studies; populations with individually identifiable data; and investigator conflicts of interest. Through this emphasis on specific research-related areas (which did not exist in NHRPAC's charter), the HHS Secretary has attempted to focus SACHRP's attention on particular issues which are important to the current administration's agenda.

During the inaugural meeting, a priority-setting discussion explored the areas emphasized in SACHRP's charter, along with some other topics included in the meeting agenda or introduced by committee members. As a result of this discussion, the Committee decided to form three subcommittees: one to explore issues regarding research involving children, a second to explore issues regarding research involving prisoners and a third to examine the issue of private accreditation of human research protection programs. The full Committee plans to meet three to four times per year, although the date of its next meeting has not yet been published. ■

Is There a Role for Federal Involvement in the Accreditation of Human Research Protection Programs?

By Deborah Guiffre

Accreditation programs are well established within the U.S. health care delivery system. These programs exist to set quality and safety standards of care and to assess organizations and programs relative to these standards. They seek to provide a means for continuous improvement within organizations. The two notable accrediting bodies are the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Committee for Quality Assurance (NCQA), both private, not-for-profit organizations. Founded in 1951, JCAHO evaluates and accredits nearly 17,000 organizations and programs including hospitals, home care organizations and laboratories. Joining JCAHO two decades later, NCQA has become an im-

portant accrediting body with its efforts primarily focused on managed care plans and the evolution of HEDIS, a performance measurement tool now used by more than 90% of the nation's plans.

Early in their implementation, accreditation programs offer some means of comparison among organizations. Over time, they serve to promote higher quality across the system. Although accreditation represents a form of voluntary self-regulation and is not backed by law, there are incentives that encourage participation. For example, more than half the states recognize NCQA accreditation as meeting certain regulatory requirements for health plans, obviating the need for a separate state review. Similarly, to participate in Medicare and/or Medicaid programs, hospitals, nursing homes, home health agencies and clinical laboratories must be accred-

Does the Growing Role of Contract Research Organizations and Site Management Organizations Threaten the Integrity of Human Subject Recruitment Practices?

By Marlene G. Krammer

In an attempt to reduce research and development costs and expedite clinical trials, drug companies have increasingly turned away from academic medical centers in favor of for-profit contract research organizations (CROs) and site management organizations (SMOs). In 1991, 80% of pharmaceutical industry expenditures for clinical trials went to academic research centers; by 1998 this amount had dropped to 40%.¹ CROs offer manufacturers a menu of drug development services; drug companies may outsource the entire development process or only individual components. SMOs organize networks of community physicians to act as clinical trial investigators and thereby gain access to their patients as potential study subjects.

The increasing use of CROs and SMOs raises certain issues which should be of concern to the research community. While these issues were not discussed at the meeting—and do not appear to be on SACHRP's current agenda—I believe they merit discussion and attention. One of the most serious involves research subject recruitment practices.

There is no independent federal oversight of CROs and SMOs, although their activities are indirectly controlled by federal law through sponsor regulation when they are performing trial-specific activities on behalf of drug companies. CROs and SMOs often enlist research subjects directly through their websites, and it is there that the most inappropriate volunteer recruitment practices in the research community can be found.

The improper recruitment practices primarily involve two strategies: (1) emphasizing financial compensation and other perks of participation and (2) blurring the line between research and treatment (known as “the therapeutic misconception”). Both the Office of the Inspector General (OIG) and the FDA consider subject recruitment to be the first step in the informed consent process.^{2,3} The OIG notes that misleading information contained in recruitment materials may shape subjects' initial judgments about a research study and thereby influence their decisions about participating. Moreover, the therapeutic misconception can be particularly difficult to clarify after the formation of

a potential subject's initial impression.⁴ These considerations should be kept in mind when reading the following striking examples of inappropriate recruiting messages which I found on CRO and SMO websites. They clearly play to the lure of either participation perks or the therapeutic misconception.

Perks of Participation

- “Study participation is fun, easy and a great way to earn extra money.”⁵ “Hill Top Research is the perfect fund-raising vehicle for non-profit groups.”⁶
- “The Novum Experience is PROFITABLE because you can earn money easily in your spare time.”⁷ “In the past, payments have ranged from \$170 to \$3,000. Last year, Novum paid 1.4 million dollars to over 2,000 people who participated in a Novum research study.”⁸

These statements, which emphasize financial remuneration and ignore risk, are unbalanced, misleading and potentially coercive, particularly to individuals with the greatest financial need.

The Therapeutic Misconception

- “The Novum experience is HEALTHY because you receive a free screening physical.”⁹
- “Research volunteers receive at no cost: A thorough medical evaluation and extended follow up care. Comprehensive laboratory evaluations and study related procedures.”¹⁰ “A number of participants have benefited from study related care by identifying previously undetected, underlying conditions; including, lung and breast cancer, diabetes, high cholesterol, and various other abnormal conditions.”¹¹
- “Volunteers receive free, ‘state of the art’ medical evaluations, treatment, and diagnostics during study participation - in most cases.”¹²

The promise of “thorough” medical evaluations, “extended” follow-up care and “comprehensive” laboratory evaluations is inaccurate and misleading; clinical evaluations will be limited to study-specific parameters, and little or no follow-up care may be provided. These statements are deliberately designed to use the therapeutic misconception as a lure to induce participation. Individu-

als without adequate access to health care are especially vulnerable to these tactics.

The pharmaceutical industry's growing reliance on the services of CROs and SMOs, and the absence of independent federal regulation over their activities, have the potential to substantially undermine the clinical trial informed consent process. Given the lack of clinical research ethics evidenced in the subject recruitment practices of even some of the largest CROs and SMOs, it appears that only federal regulation—or the threat thereof—will cause these companies to reform their practices.

As members of the public were invited to submit materials to SACHRP for its consideration prior to the inaugural meeting, I sent the committee a letter drawing their attention to the unethical recruitment practices utilized by certain CROs and SMOs. This topic was not addressed at the inaugural meeting, however, and, given the currently established priorities of the committee and the administration, there is no reason to believe that it will be addressed soon.

Marlene Krammer, an attorney, will receive her MA in Health Advocacy this month. She is particularly interested in areas of bioethics and human subject research.

¹Bodenheimer, T. “Uneasy alliance: Clinical investigators and the pharmaceutical industry.” *Health Policy Report* Vol. 342, No. 20 (May 18, 2000):1540.

²DHHS (Department of Health and Human Services), Office of Inspector General. OEI-01-00195. “Recruiting Human Subjects: Pressures in Industry-Sponsored Clinical Trials.” June 2000:8 www.oig.hhs.gov/oei/reports/oei-01-97-00195.pdf (accessed 11/21/03).

³FDA (Food and Drug Administration). “Recruiting Study Subjects.” Guidance for Institutional Review Boards and Clinical Investigators, 1998 Update. www.fda.gov/oc/ohrt/irbs/toc4.html (accessed 11/21/03).

⁴DHHS:20-21.

⁵www.hill-top.com/studies/index.html (accessed 11/01/03).

⁶www.hill-top.com/studies/fundraising.html (accessed 11/01/03).

⁷www.novumpr.com/ (accessed 11/01/03).

⁸www.novumpr.com/Pittsburgh/fspitt.htm (accessed 11/01/03).

⁹www.novumpers.com/ (accessed 11/01/03).

¹⁰www.acr-research.com/volunteer_info.htm (accessed 11/02/03).

¹¹www.acr-research.com/patients.htm (accessed 11/02/03).

¹²www.gulfcoastr.com/voluntee.htm (accessed 11/02/03).

Beyond the Bull's-Eye: Advocates Take Aim at Lyme Disease

Continued from page 9

symptoms. Dr. Bunnell says, "Having a patient who is cognitively limited, often in terms of language, trying to articulate a complicated phenomenon loaded with subjective assessments (Am I anxious? Am I thinking clearly?) to someone who doesn't have the time to listen is a setup for failure."

Complaints about memory may be attributed to stress, depression, menopause or Alzheimer's disease. Deficits may be especially troublesome to assess in children and the elderly. Doctors have screening tests they employ during office visits to gauge memory loss, but, Drs. Bunnell and Fallon agree, these can miss significant disabilities. Neuro-psychological testing explores all aspects of memory in detail, but, according to Dr.

Bunnell, can also be traumatic for the impaired—a "psychological spinal-tap."

Treatment

Patients who fail to respond to standard antibiotic doses challenge physicians, since the nature of ongoing symptoms has provoked contradictory interpretations. Some researchers believe persistent problems are caused by an active infection. Others theorize they represent an immune or inflammatory response to an infection that has been cured. Patients who research their illness find themselves thrust into a complex medical argument. Dr. Bunnell believes patients must educate themselves, but knows that is terribly difficult to do without medical training—especially

while sick with fatigue, pain and/or cognitive limitations.

For example, treatment guidelines issued by the Infectious Diseases Society of America in 2000 (accessed at its website 11/03) recommend 14 to 21 days of oral antibiotics for early Lyme and two to four weeks of intravenous therapy for neurological disease. The report states: "Response to treatment is usually slow and may be incomplete. However, unless relapse is shown by reliable objective measures, repeat treatment is not recommended." Dr. Gary Wormser (Chief, Division of Infectious Diseases, New York Medical College, Valhalla), co-author of the report, noted: "The consensus

Continued on page 13

Is There a Role for Federal Involvement ... ?

Continued from page 10

ited by either JCAHO or a state Department of Health.

Two private, not-for-profit groups have emerged in the arena of accreditation for human research protection programs. These groups will address growing public interest in the adequacy of human research protection and the need for researcher accountability that has arisen from a series of adverse events in recent studies. (See accompanying article by Marlene Krammer.) In principle, both the federal Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA) have supported private accreditation as a component of an overall strategy to better protect human research participants.

The first group is Partnership for Human Research Protection (PHRP). Interestingly, PHRP is a partnership of JCAHO and NCQA. The second group is the Association for the Accreditation of Human Research Protection Programs (AAHRPP). AAHRPP is an outgrowth of Public Responsibility in Medicine and Research (PRIM&R). Both share an overall goal of developing performance standards that encourage programs to adopt best practices and to recognize the programs that meet these standards. This philosophy differs from that of compliance with minimum federal standards. Voluntary assessments have both self-assessment and peer-review compo-

nents and will address standards in:

- Institutional responsibilities
- Institutional Review Board (IRB) structure and operations
- Consideration of risks and benefits
- Informed consent

Several SACHRP members are active in one of the groups and involved in the ongoing development of program standards and assessment processes. Consequently, considerable passion was exhibited about this topic during the SACHRP inaugural meeting. At the heart of the discussion was what, if any, role SACHRP, OHRP and FDA might play in advancing meaningful accreditation and encouraging institutions to become accredited. There was a palpable sense of pride and protection of the particular programs that members represented.

As experts on the subject, several members of the Committee plunged into the minutiae of the topic. For example, there was a lengthy discussion about the merits of accreditation and ways to reward institutions that become accredited. Similarly, Committee members detailed challenges in collecting and interpreting accreditation data. Finally, the group embarked on a discussion about whether SACHRP should certify accreditation bodies. Bear in mind that neither program has been implemented or assessed for its impact on human research protec-

tions. The standards for each of these groups differ. These differences have not been identified, critiqued or analyzed. In their zeal, the group clearly put the cart before the horse.

At the conclusion of this discussion, the Committee chair moved that SACHRP establish a subcommittee on accreditation. Its goals will be to examine the background of accreditation, look at the organizations that are embarking on IRB accreditation, review the possible benefits of accreditation and recommend roles for DHHS—specifically OHRP and FDA—in the accreditation process. A notable omission from these goals is the need to develop metrics that will allow for assessment of the impact of accreditation on human protections.

As of this writing, no subcommittee activity has commenced. An interesting side note to this topic is the announcement in a September 30, 2003 CDC press release that it has awarded a three-year grant to AAHRPP to assess the role of accreditation in enhancing the protection of participants in public health research. One must wonder if this organization has gained a leg up in the heated world of human research protection accreditation programs.

Deborah Guiffre, a current HAP student, is particularly interested in health care policy and community organizing. ■

Beyond the Bull's-Eye: Advocates Take Aim at Lyme Disease

Continued from page 9

reached by the expert panel was that, to date, there are no convincing published data that repeated or prolonged courses of either oral or intravenous antibiotic therapy are effective....We also concluded that there is insufficient evidence to regard 'chronic Lyme disease' as a separate diagnostic entity."

Conversely, the International Lyme and Associated Diseases Society (ILADS) states on its website (accessed 11/03): "A preponderance of evidence indicates that active ongoing spirochetal infection is the cause of persistent symptoms....There has never in the history of this illness been one study that proves...30 days of antibiotic treatment cures Lyme disease." ILADS contends "uncomplicated chronic Lyme...requires an average of 6 to 12 months of high-dose antibiotic therapy...until the patient is symptom-free."

Thousands of patients believe long-term antibiotics have been essential to their recoveries or to their abilities to manage incapacitating symptoms. However, probes have been conducted in several states, threatening clinicians who treat Lyme aggressively with the loss of their licenses. Patients are upset by these investigations, worried doctors will not feel free to find treatments that work.

Insurance companies—not all, but some, according to Dr. Fallon—prefer not to pay for long-term treatment. Negative testing can be used to deny coverage; Dr. Fallon has even seen positives dismissed as false positives. He believes many doctors are now wary of prescribing IV—although studies point to its efficacy—and are using orals instead, because they fear being flagged by insurers or conservative colleagues.

Connecticut Attorney General Richard Blumenthal received so many complaints that in February, 1999, he held a hearing. He stated then: "My office has received scores of...moving, incisive accounts of health insurers denying coverage...or rejecting doctors' diagnoses....The number and severity of complaints—some extraordinary horror stories—suggest there must be a complete review so as to assure acceptable coverage." The hearing did in fact result in a protective legislative mandate. The law provides specific treatment guarantees; additionally, long-term therapy is covered if recommended by certain specialists. Unfortunately, patients have had difficulty obtaining such

opinions on the basis of clinical symptoms alone.

Financial impact

Financial stresses add to the burden of patients already overwhelmed by illness and controversy. Marcy quit her job to care for Paige. Jane's family incurred hundreds of thousands of dollars in medical expenses. Dr. Fallon has seen "enormous numbers" of Lyme patients struggle financially due to disability, lost productivity or rejection of coverage by insurers; some sufferers have even lost their homes. Economic implications extend beyond the family to the community, as schools face rising special education budgets and employers cope with impaired workers.

Mary

A nurse in Fairfield County, Mary was well aware of Lyme when in October, 1999 she removed an engorged tick. Within 48 hours, she developed flu-like symptoms and a bull's-eye rash. Her doctor immediately prescribed one month of antibiotics. By January, however, Mary was ill with migratory joint pain, fatigue and chills. Antibody tests were negative but her doctor, convinced Lyme was the culprit, treated her for eight more weeks. Months later, Mary developed cognitive and memory impairment. Tests were again negative. She began having tremors, muscle weakness, numbness, balance and coordination problems, neck pain, headaches and stammering speech. She was unable to work or drive. "I would know to stop at a stop sign, but I would forget to look both ways....I kept getting lost in town, going to places I go all the time." An emergency room physician believed she had MS, but Mary insisted that Lyme be ruled out. Brain-imaging techniques showed Lyme-like changes (although these tests, too, are not definitive). Mary improved with more orals, but was still so ill she received 23 weeks of IV.

Despite her medical training, the experience was extremely difficult. Although normally confident, she was afraid to assert herself. While pleased with her care overall, Mary was incredulous when doctors failed to classify her plight as an emergency. She asked them, "If this was your wife, what would you do? I'm trying to raise three children here....I can't remember their names, I forget them when...I have to go get them....I don't understand how you can

feel this is not important."

Today, Mary is "95% better," although she struggles periodically with headaches, numbness and word-retrieval issues. Nevertheless, she handles her demanding job and will soon obtain a master's degree. Despite losing her gallbladder to IV treatment, she uses her nursing position to promote long-term treatment for symptomatic patients.

Research

Dr. Fallon hopes to put many of these controversies to rest with his research. With \$4.7 million in funding from the National Institute of Neurological Disorders and Stroke, he is studying long-term antibiotic treatment. His investigations will likely clarify diagnostic issues, too. He urges patients to apply for "the best neurological Lyme work-up in the world."

Patients, too, are working toward scientific solutions by supporting various non-profit initiatives. For example, the Lyme Disease Association is funding a Lyme center at Columbia University. The Lyme Disease Foundation sponsors an annual scientific conference. The National Research Fund for Tick-Borne Diseases awards grants to researchers at preeminent academic institutions.

Conclusion

Every month, we have new visitors to our support group. Recently, we saw a friendly young man in a wheelchair, unable to walk; a 20-something woman with such severe cognitive problems, she was accompanied by her parents; and a mother whose entire family is ill with a multitude of symptoms. In fact, it is not uncommon in Fairfield County to see several family members chronically affected. Dr. Bunnell is perhaps most moved by parents who come on behalf of their children. Youngsters have a fundamental need to feel safe. Having Lyme violates that need: "You mean, something in my backyard can make me sick?" It has "long-standing ripple effects" that impact relationships, inhibit experiences and threaten cognitive impairment. "The most tragic thing is seeing a kid whose life may now be forever affected by a tick bite."

Yvonne Bokhour is a student in the HAP. For information about Dr. Fallon's study, the Wilton Lyme Disease Support Groups or other aspects of this article, she can be contacted at kos1@earthlink.net. ■

A Friend in Need: How a Small Program Can Make a Big Difference

By Betti Weimersheimer

Family Friends, an intergenerational program created in 1986 by the National Council on Aging, matches volunteers aged 55 and older with children and families in need. There are currently 35 Family Friends programs nationwide. While originally designed to serve children with disabilities and chronic illnesses, today Family Friends programs also reach out to children who are disadvantaged, homeless or otherwise "at risk."

In March, 2001, I was hired by Mount Sinai Medical Center in New York City to create Family Friends within the hospital setting. Dr. Danielle Laraque, Chief, Division of Pediatrics, was awarded a three-year grant from the Department of Health and Human Services Administration on Aging to develop a Family Friends program at Mount Sinai. She had previously started the program at Harlem Hospital Center, where it is now in its sixth year of operation.

The Mount Sinai program serves families in East and Central Harlem. Its mission is to provide support to families overwhelmed by socioeconomic and medical issues who can use the guidance and experience of an older adult from within their own community to ease some of the stresses in their lives.

Starting Up

I recruit, train and supervise the volunteers. After 20 hours of training (training materials are provided by the National Council on Aging), the volunteers are matched with a family. They visit the families in their homes for two to four hours a week, where they offer assistance by listening, reading, tutoring, playing games and providing stability and friendship. The volunteers give much-needed respite to parents exhausted by caring for a child with special needs. The parents or caregivers gain both time for themselves and a supporter to listen to their problems and help them cope with issues they may be facing.

Establishing a program such as this within a hospital bureaucracy is no easy task. I did not have an office, telephone or computer for three months. I carried

my papers and computer disks with me and found access to computers whenever and wherever they were available.

At first, the primary goal was recruiting volunteers. The program is a hard sell, especially since I was asking volunteers to go into people's homes, get emotionally involved with a family and make at least a nine-month commitment to visit that family. The location of the families—a low-income, minority neighborhood with a reputation for high crime rates—limited the recruitment of volunteers from outside the area.

The good news is that there are currently 19 volunteers in the program. All except two live in East Harlem. Most visit families in their homes, while about



Volunteer Katherine Horne reads to Eric Hayes at the Family Friends art party

a third work with them at the Pediatric Primary Care Practice, a clinic that sees approximately 10,000 patients each year. Some have been visiting the same families for close to two years.

The Families

All of the families in the program are low-income, most headed by single mothers. They are all members of minority groups, many of them immigrants who are undocumented and non-English-speaking. Some live in substandard housing crowded with other families in order to share rental costs. All are Medicaid recipients or uninsured. Besides being economically disadvantaged, many are exposed to divorce, domestic violence and other psychosocial stressors.

The age range of the children is 0-12, with most falling between three and

nine. Thirty-five children are served in their homes. Some spend time with the volunteers while waiting to see a doctor at the Pediatric Primary Care Practice.

The families in the program often rely on the volunteers to help them access much-needed services. Because of their limited English, many feel too intimidated to seek the help they require or push for their children's right to services legally available to children with disabilities in the schools. In such situations, the volunteers can be especially helpful in advocating for the families. By acting as role models, they also empower the parents to start advocating on their own behalf. Sometimes the volunteers act as translators for non-English-speaking parents who need assistance navigating the city's education, health care and social services systems. I also get calls from parents for help with Medicaid issues or referrals for doctors, social workers or psychologists.

The Volunteers

The majority of the volunteers are very low income seniors. Most live in East Harlem in subsidized senior housing or in housing projects where the rent is set by income. They all have their own medical difficulties and I try to gear the monthly in-service meetings to issues that affect aging adults, such as diabetes, Parkinson's disease, Alzheimer's disease, asthma, osteoporosis and depression. Fortunately, I have the staff of a large hospital to tap into, and there is never a shortage of specialists to address the seniors on a variety of topics.

Of course, we also discuss the families with which the volunteers work so they can share successes and disappointments and obtain the feedback of their peers. The volunteers need a lot of nurturing on my part, which I gladly do because they are wonderful people and I enjoy spending time with them. Some are more independent than others.

Carolina lives in Staten Island. She is 73 and originally from Ecuador, where she was an economist. She rents a room in a house where she has to share the bathroom and kitchen. She has no phone of her own. Carolina awakens at 3 a.m. to get to her job in Manhattan, where she

New HAP Group Focuses on Health Policy

By Jane Nusbaum

The Health Advocacy Program has formed a Policy Working Group to address local, county, state and national government issues. Its focus:

- **legislation**—proposing, passing, implementing and enforcing
- **the budget process**—understanding and acting on the political implications
- **coalition building** to address policy initiatives
- **public education** related to policy issues on all levels of government

Currently the Policy Working Group is investigating two action issues: (1) procedures on unconscious and nearly/newly deceased patients; (2) genetic discrimination in insurance and employment.

Procedures on unconscious and nearly/newly deceased patients

At teaching hospitals across America, medical students are using patients who are anesthetized or nearly/newly dead to practice procedures such as pelvic examinations and resuscitation techniques. The patients used for practice have been admitted for OB/GYN procedures and/or are close to death or recently deceased. Informed consent is not obtained from patients, family or proxies.

Patients generally have no idea that medical students may practice pelvic

exams, resuscitation or other procedures on them while they are unconscious, dying or dead. And, afterward, no one informs the patient or family members that these practice exams/procedures took place—neither the doctor who instructed the students nor the students who used the patient for practice. Because patients sign a general pre-operative consent form and are in a teaching hospital, many doctors and students believe patients are implicitly giving them permission to practice on them, even though there has been no explicit consent requested or obtained.

Obviously this system raises many issues of professional ethics and patient rights; but it also can enter the policy arena. California is the first state to enact legislation in this area. On October 2, 2003 Governor Gray Davis signed a bill into law requiring explicit consent from female patients before undergoing anesthesia in order for doctors and medical students to perform pelvic exams or other procedures. It is the first law of its kind in the country and passed the California Legislature without opposition. Assemblywoman Sally Leiber (D-Mountain View) was the chief sponsor. The Policy Working Group is researching and investigating similar state and federal policy initiatives.

Genetic discrimination in insurance and employment.

Genetic tests exist for hundreds of dis-

orders, allowing improved prevention, detection and treatment of diseases. Some of the most widely available tests are for women who may carry a gene predisposing them to breast or ovarian cancer. By participating in genetic research or taking a genetic test, however, they can be denied job opportunities, health care, or both, based on their genetic information.

Many states, including New York, have passed genetic discrimination laws protecting people from job and health insurance discrimination based on genetic testing results. On October 14, 2003, the United States Senate took a critical step forward in helping patients take advantage of America's advancing medical technologies when it unanimously passed S1053, the Genetic Information Nondiscrimination Act of 2003. S1053 establishes the first comprehensive federal standards to protect the privacy of genetic information and prohibit genetic discrimination in health insurance and in the workplace. The Policy Working Group is examining provisions of the Senate and state bills and working in coalition with other groups to support protective legislation in this area.

For further information and background materials, contact Jane Nusbaum at jnusbaum@slc.edu or (914) 472-4729.

Jane Nusbaum, HAP faculty consultant and social policy activist, chairs the Policy Working Group. ■

A Friend In Need: How a Small Program Can Make a Big Difference

Continued from page 14

works as a Food Emporium cashier. She visits two families in the Family Friends program, takes ESL classes and also volunteers in a soup kitchen in Chelsea once a week. I doubt she gets more than four hours of sleep a night. Always cheerful, she would gladly take on another family if I asked her to do so.

Carolina has no health insurance. A few months ago she fainted after leaving work and was taken to an emergency room. She had to pay the bill from her meager income of \$14,000 a year. I have been trying to find her lodging in Manhattan and she is on several waiting lists for senior housing. It could take years before an apartment is available, however. Nevertheless, she retains her in-

domitable spirit. Carolina truly is a special person. She says the program has been good for her because it brings her into contact with families from other cultures. "I feel grateful that I can be part of the families I visit because my daughter and grandchildren are in Ecuador and I don't see them very often. Everyone benefits from the program—the child, the family and especially me."

What amazes me about the volunteers is that, despite their own hardships and medical issues, they are willing to give so much of themselves to help others who desperately need the extended support system they so generously provide.

A Case Study

Ruth, one of the volunteers, was matched with a Mexican family with

three boys: an infant, a four-year-old and an eight-year-old. The family lives in a sixth-floor walk-up in a building needing many repairs. It shares the apartment with another family with two children. None of the adults speaks English. The four-year-old was having problems at home, acting aggressively, not eating, sleeping very little. Apparently he had no behavioral problems at preschool, although it was obvious to me and to Ruth that he had trouble concentrating and remembering letters and numbers.

Upon questioning the mother, Ruth learned she was giving the four-year-old coffee at night, as well as soda and sugary snacks, because he refused to eat the meals she prepared. Ruth suggested that her son was probably having sleep difficulties because of the coffee. The father

Working Together to Improve the End-of-Life Experience

Background

In 2001-2002 the Health Advocacy Graduate Program at Sarah Lawrence College and the Service Board of Jansen Memorial Hospice jointly organized "Understanding the End of Life," a series of six educational programs for the public. The sessions were very well attended by concerned citizens and professional health care workers from around Westchester County. All expressed the need and desire to improve the end-of-life experience in our community. **The Westchester (NY) End-of-Life Coalition** was founded to build on the interest and energy this series created and to promote a community-based approach to end-of-life care. It is part of the Rallying Points nationwide network of community coalitions.

Vision

A community where all those with life-limiting conditions are able to die with dignity, at peace, pain-free, in a place and manner of their choosing; a community where persons who are dying and their families receive competent, compassionate and timely care and support.

Mission

- Educating the community about

end-of-life issues and expanding awareness of the importance of these issues.

- Informing the public about available services related to end-of-life care by functioning as a clearinghouse and a conduit for networking.
- Identifying the gaps in services and promoting the establishment of services that will fill those gaps.
- Promoting a community where the dying and their caregivers receive the medical, social and spiritual support they need.
- Advocating with policy makers and legislators for laws and regulations that will improve the end-of-life experience.

The Coalition is mindful of the need to reach all residents in our ethnically and economically diverse community and to communicate at all levels of health literacy.

* * *

The following WEOL Coalition community education programs will take place in 2003-2004:

Study Group: Informal discussions based on the Hastings Center publication, *Access to Hospice Care: Expanding*

Boundaries, Overcoming Barriers. Jane Nusbaum, HA '93, facilitator. Monday evenings, December 8th, January 26th, March 8th, 7:30-9:00 p.m., Slonim House.

This report addresses problems of access to and delivery of hospice care. It also focuses on the human values in hospice care policy and practice, as well as organizational forms through which to express those values. Bruce Jennings from the Hastings Center will attend the March 8th meeting. A copy of the publication is available at www.thehastingscenter.org. For more information, contact Jane Nusbaum at jnusbaum@slc.edu or (914) 472- 4729.

Death and Dying in Himalayan Cultures, Robert R. Dejarlais, Anthropology faculty, SLC. February 2, 2004, 7:00 p.m., Slonim House.

Third annual theatre production and discussion co-sponsored by the SLC Theatre Department, the HAP and the Westchester EOLC, Spring 2004; watch the HAP website for announcements.



A Friend In Need: How a Small Program Can Make a Big Difference

Continued from page 15

blamed the mother because the boy was not eating. Then she gave in to her son when he wanted junk food to appease them both. The mother became so worried that Ruth eventually accompanied her and the boy to the emergency room for a psychological evaluation.

The hospital social worker attributed the underlying problem to the boy's attempt to control his mother and let her know he needed more attention. The next time Ruth visited, instead of spending time with the four-year-old, she took care of the infant and let the mother spend time with her middle son. This arrangement produced a marked change in his behavior. It has not been as easy to convince the mother that coffee and Coke are not good for him; that will probably take time as trust builds between Ruth and the mother and she realizes that certain interventions will improve her son's behavior and attention.

Ruth has also benefited greatly from the program. She suffers from depression, is on medication and, until recently, received disability benefits because of her inability to work due to her illness. She says, "Volunteering for Family Friends helped boost my confidence and made me feel better about myself when I saw I could be of help to someone else." Not long ago, Ruth was hired as a counselor by a New York City agency.

Looking Ahead

The biggest obstacle currently facing the program is financial. Dr. Laraque's three-year grant ended on September 30, 2003. Because the program got a late start, we received a no-cost extension for nine months. That leaves only enough funds to pay my salary and benefits and to reimburse the volunteers for travel expenses. My attempts at raising money have so far met with dismal results. I have applied to a number of foundations with no luck. Fortunately, I receive in-

kind donations of books, art supplies and toys for the volunteers to take to the children. These are tough times to raise money. Although Dr. Laraque will do everything she can to keep the program going, the hospital, with its own financial problems, will not contribute to its funding. Family Friends does not generate income for the hospital and, while it provides a valuable community service, is not a priority.

I now spend much of time writing grant proposals and seeking donations. The volunteers and I try to remain optimistic that somehow the program will receive the necessary funding to keep it alive. I have a feeling that a number of the volunteers will maintain their relationships with the families with which they have been matched even if the program is forced to shut down.

Betti Weimersheimer, HA'00, works with Family Friends and is a research associate at the Mount Sinai School of Medicine. ■

Communicating with Children and Adolescents with Life-Limiting Conditions

A forum co-sponsored by the Health Advocacy Program and the Westchester (NY) End-of-Life Coalition

By Nathan Ionascu, MD

This forum, held November 4, 2003, grew out of discussions among WEOL Coalition members about the difficulty many professionals experience in talking to children with life-limiting conditions and the need to respect these children's own knowledge and desires as their autonomy emerges during adolescence. We drew together a panel of clinicians, researchers, parents and advocates representing a wide range of academic and practice fields and of life experiences. The program was ably moderated by Dr. Nancy Green, Medical Director of the March of Dimes, a pediatrician and pediatric hematologist/oncologist. She brought a balance to the evening dialogue among the panelists and between the panelists and the audience. The audience of more than 60 people, including a number of SLC students, also reflected this breadth of disciplines and ways of connecting with children.

The Panelists

Nicole Asselta, CSW. Visiting Nurse Service of NY (Nassau); chairman, Outreach Program of the Parent Resource Center, Port Washington, NY.

Fred Epstein, MD. Founding director, Hyman-Newman Institute of Neurology and Neurosurgery, Beth Israel Medical Center. Author of *If I Get to Five*.

Kenneth Gorfinkle, PhD. Assistant clinical professor of psychology and psychiatry, Columbia University College of Physicians & Surgeons and New York-Presbyterian Medical Center. Author of *Soothing Your Child's Pain: From Teething and Tummy Aches to Acute Illness and Injuries*.

Maggie Hoffman, Advocate. Co-director, Project DOCC (Delivery of Chronic Care), a family-centered, community-based pediatric

training program that focuses on the impact of chronic illness and/or disability on individuals and their families.

Linwood Lewis, PhD. Psychology faculty, SLC. Especially interested in effects of culture and social context on conceptualization of health and illness; has been conducting research on adolescents with HIV/AIDS.

Alex Okun, MD. Pediatrician and associate professor of clinical pediatrics, Albert Einstein College of Medicine; founder and director of the Linking Individual Needs of Children with Services (LINCS) Program, Children's Hospital, Montefiore Medical Center.

Michael Rowe, PhD. Associate clinical professor of sociology, Yale University School of Medicine's Department of Psychiatry; Co-director of the Yale Program on Poverty, Disability and Urban Health. Author of *Book of Jessie*.

Tania Shiminski-Maher, Pediatric nurse practitioner, Hyman-Newman Institute of Neurology and Neurosurgery, Beth Israel Medical Center. Co-author of *Childhood Brain and Spinal Cord Tumors: A Guide for Family, Friends, and Caregivers*.

Penny Wolfson, PhD. Creative writing faculty, SLC. Author of *Moonrise: One Family, Genetic Identity, and Muscular Dystrophy*, detailing her thoughts, the family's experiences, and her research for a better understanding of the disease.

The Discussion

After introductory remarks, the panel

and audience engaged in a dynamic discussion. Themes of the evening included:

Communication. Parents need help communicating with a child whose disease is life-limiting. In particular, they want to know whether, how and when a child wants to communicate. Nobody should push the subject upon the patient, but careful, active listening is essential. Answers to questions should be brief and to the point. Level of understanding, maturity and development should be considered. Often, a child will initiate dialogue with a member of the healthcare team with whom he feels comfortable. A child life specialist or a music or occupational therapist may help him express fears, concerns or feelings through art, singing, or play.

Support Services. There is a great need for support services beyond the medical team for patients and families, both in the hospital and in the community. The harsh blow of a life-limiting diagnosis in a child is devastating for anyone, but much more so for single-parent, poor, minority families whose English-language skills may be minimal. Cultural, ethnic and language issues are magnified for these families, as well as for the patients.

Palliative Care. Some dying children, for various reasons, cannot go home. There is very little that a hospital environment can offer these patients and their families to facilitate death with dignity, surrounded by the love of those the child holds dear. A few children spend the end of life in an ICU—a very cold, technology-driven environment. Dr. Joelle Mast, pediatric neurologist and medical director of Blythedale Children's Hospital, cited efforts under way to provide palliative and hospice care for these children, even in an ICU, to alleviate



Panel from left to right: Maggie Hoffman; Michael Rowe; Nicole Asselta; Linwood Lewis; Nancy S. Green; Alex Okun; Penny Wolfson; Tania Shiminski-Maher; Fred Epstein. Kenneth Gorfinkle is not pictured.

Medical Errors: The Role of the Patient Representative

Continued from page 4

culture defines whether honest, open and non-defensive disclosure discussions can occur. The institution's ethical commitment to patients' rights in this context must derive from top administration and be driven by senior physician leadership in an atmosphere that supports clinicians who participate in disclosure discussions. Junior physicians need opportunities to model senior physicians in truth-telling situations. It is not an easy thing to do well, and physicians are often met with anger or grief that they may be ill-equipped to handle. The role of the advocate is to encourage and support individual clinicians in this difficult duty and to influence institutional leadership toward fostering a culture in which disclosure discussions are valued rather than resisted.

Advocates can use institutional self-

interest to influence leadership. The single most powerful barrier to openness about errors is fear of legal risk; advocates can argue that openness is an asset in potentially litigation-prone situations. Patients feel that inadequate time with and communication from physicians is the most important problem with health care.⁴ In addition, patients' dissatisfaction with quality and quantity of communication from providers is a component of their incentive to sue.⁵ Errors do not necessarily constitute negligence or unethical behavior, but failure to disclose them does. If patients discover details relating to errors that were not openly discussed with them, the provider's potential guilt is compounded by this failure.

Granted, patients typically do not sue for lack of communication alone. However, it is known that patients are more likely to sue non-communicative physicians who injure them as a result of a

medical error, and less likely to sue communicative physicians who injure them. The variable seems to be accessibility and willingness to be open and forthcoming with information. Openness about medical errors may be one of those increasingly rare situations where the advantage to the institution coincides with the rights of the patient.

Laura Weil, co-teacher of the HAP course Models of Advocacy: Theory and Practice, is director of the Patient Representative Department, Beth Israel Medical Center, NYC.

¹Witman, *Archives of Internal Medicine*, 1996; 156 (22):2565-69.

²Hingorani, *British Medical Journal* 1999;318:640-641.

³Ibid.

⁴Blendon, *New England Journal of Medicine* 2002; 347 (24): 1933-40.

⁵Ambady, *Surgery*, 2002; 132 (1):5-9. ■

Breast Cancer

Continued from page 8

tics year after year. This is the first and only federal program designated for new and innovative approaches, and administrators believe consumer advocate involvement has helped keep it on track. Through fiscal year 2001, Congressional appropriations for breast cancer research totaled \$1.2 billion, and more than 2,800 awards have been made to facilitate research aimed at "the program's vision to eradicate breast cancer."

Looking Ahead

As long as consumers with direct experience with breast cancer (or another disease) are involved in the review process, I believe that appropriate research will be supported. Being there keeps us aware of what new approaches get funded, how the process works and what the goals are. Having a voice ensures that we'll influence research to impact women's health now and into the future. The way the DOD conducts this program, the process, and the quality of the submitted proposals are unique. I'm glad I was able to be involved this year and look forward to the chance to serve as a consumer reviewer again.

Jane Baker Segelken travels from Ithaca every week to pursue graduate studies in the HAP. ■

Communicating with Children

Continued from page 17

their isolation and suffering.

Depression. The subject of depression in these children, especially in adolescents, was discussed at some length. Many do not want to talk about death and dying, preferring to live as normally as possible for as long as possible. Children appear to handle bad news much better than adults, able to concentrate on the here and now, trying to accomplish what matters to them in the moment. They can hold two realities: knowing they are going to die, yet living life in ordinary and fulfilling ways. Thus, they often seem very pragmatic.

Stigmatization. Children with a life-limiting condition may be stigmatized because of their illness or its disabling effects. Schools seem to do well teaching about differences among children in primary grades, but "drop the ball" when it comes to middle school. This makes it especially difficult during early adolescence for those youngsters who can attend class—and wish to do so—but are ostracized by their peers. Advocate Maggie Hoffman directs a helpful program in which middle school children who are sick or disabled form a panel that talks to peers in other schools to sensitize them to this problem.

Teams. A number of panelists raised

the subject of medical teams—both the benefits of the team approach and its weaknesses. Teams may in fact be another form of fragmentation for families of very sick children. No one person is there to coordinate the care, to be the "captain of the ship." Penny Wolfson said that primary care doctors should assume this role, but, in tertiary care teaching centers, they are often not involved. Instead, specialists, fellows and residents provide the care, even after the patient returns home. Even when all team members are involved with both child and family during the last stage of illness, panelists and audience members were concerned about the abandonment parents feel after the child has died. Caregivers who have an intense relationship with healthcare professionals while their child is sick and dying often feel deserted by them after his/her death.

Education. Panelists felt that educating professionals about caring for children near the end of life needs to start early in medical and nursing school curricula. Students should be taught about the responsibility they have as professionals when they become intimately involved in the care of patients with life-limiting illness. This is even more so when the patients are children and the diagnosis represents such a blow to their families. Some healthcare professionals

From the Director...

By Marsha Hurst

The "Patient's Bill of Rights" of the American Hospital Association (AHA) was first adopted in 1973. In many respects, it is the foundation of the early patient advocacy movement: Promoting and protecting patients' rights form the core of professional patient advocacy.

In 2001, the AHA convened a task force on "A Patient's Bill of Rights" because member associations, including the Society for Healthcare Consumer Advocacy, felt there was a need to move away from the "Bill of Rights language." The conclusions of the Task Force, since implemented by AHA, constituted a significant reframing of patient rights, as reflected in changes of tone, content and title. Tone changes were in the direction of "consumer-friendly" language about teams, partnerships, encouraging communication between patients and providers. The content moved away from "rights," which were considered regulatory, and toward expectations. And the title moved away from the "Patient's Bill of Rights," which was considered too "legalistic." The new document is called "The Patient Care Partnership: Understanding Expectations, Rights and Responsibilities."

The language of rights empowers the patient. You are entitled to information about your condition, to make informed decisions about your care, to name a

proxy if you are mentally incapacitated, to privacy and confidentiality and so forth. This is very different from the language of partnership, a language that says the patient can "expect" information and communication, privacy, a clean environment. Unless the patient is aware of rights guaranteed by other healthcare regulations—HIPAA privacy rights, for example—s/he can only hope expectations will be met, but has no independent source of authority to turn expectations into reality. A bill of rights is a tangible foundation, one you can always use to call others accountable for their actions toward you.

Certainly we could argue that patients play more of an active role in their care than they may have before the internet distributed access to medical information more equitably, before the rights-based movements of the 1960's and 1970's challenged professional hegemony, and before managed care severed the strong but paternalistic bonds between many patients and their doctors. But to frame doctor-patient interaction in the language of partnership is to ignore the inequalities of power and position between the two and the subject position in which illness and hospital structure put the patient.

In our Models of Advocacy course, one of the modules we teach is a "rights-



based approach" to healthcare. The AHA moved away from the "Patient's Bill of Rights" in part because the language of patient rights was becoming confused with legislative mandates for patient rights. We could, however, make the reverse argument: the language of rights in healthcare is becoming more familiar to patients and healthcare consumers, which means that they will begin to think in terms not of expectations, but of promises—promises that we as advocates will make sure are kept, promises that all too often have been broken.

Instead of continuing with my own personal treatise on patient rights, I invite our readers to weigh in on this subject. You can find both the old AHA "Patient's Bill of Rights" (1993 version) and the new "Patient Care Partnership" on the AHA website, or just write in to tell us what a rights-based approach has meant for you in your work as a health advocate.

Normally I use this space to tell you more about what the Health Advocacy Program has been doing, but this issue speaks for itself, and I defer to those voices. I do want to welcome our new health economics professor, Peter Arno, who is economist and professor, Department of Epidemiology and Population Health, Montefiore Medical Center and Albert Einstein College of Medicine (NYC). He brings to the program not only a rich history of awards, research and publications, but interests that many of us share and that will become foci of his health economics course. These include: regulation and pricing practices of the pharmaceutical industry; the economics of informal caregiving and long-term care; public health and legal implications of regulating tobacco as a drug; innovation, access, quality and outcome measures related to HIV disease; and the impact of income support policies on health. Based on this work, Dr. Arno has testified before numerous Congressional committees.

Welcome, Peter. ■

Communicating with Children

Continued from page 18

find it difficult—or impossible—to face the death of their patient or communicate bad news. There is a great need for support systems for both family and professional caregivers to help them cope after a patient's death and throughout the bereavement process.

Hope. Finally, throughout the evening, people talked a great deal about hope. Michael Rowe said that hope should not be tied to "outcome." His feeling that there is no such thing as "false hope" was echoed by other panelists. A parent or professional may hope for some quality time, for palliation, for even a temporary change that treatment could produce. These hopes should be respected in decisions about medical care options. Some families, for example, wish to con-

tinue chemotherapy even if the professional team feels it is no longer curative, because, for the child, it represents hope that the tumor might still shrink. To stop the chemo would be tantamount to a death sentence: there is no hope left. While many children want to know the truth and appreciate honesty, no one should be left without hope.

The forum discussion will become the basis of a summary report on "Communicating with Children and Adolescents with Life-Limiting Conditions" prepared by the March of Dimes, the HAP and the Westchester End-of-Life Coalition.

Nathan Ionascu, a retired pediatrician, is a founding member and Executive Director of the Westchester End-of-Life Coalition. ■



Health Advocacy Program
1 Mead Way
Bronxville, NY 10708-5099
Address Service Requested

HEALTH ADVOCACY BULLETIN